Application of the Specification: There is ample, endorsed human evidence to support the patent claims:

1. Three epidemiology data sets are cited, including the Taiwan data set on internal cancers endorsed by EPA regulators by the Agency's reliance thereon and the Millard, Utah data set collected and published on by EPA scientists. The Taiwan and Utah data sets allow for the cancer (and, in Utah, heart disease) mortality comparisons of individuals exposed to "less than 50 μg/L" with those exposed to "around 50 μg/L." These comparisons demonstrate significant health benefits associated with "around 50 μg/L" compared to "less than 50 μg/L" in two very distinct population groups over extended time periods. The smaller age-matched population subsets in the Millard, Utah data set also significantly support the cancer and heart disease mortality claims made in this patent. The Cuzick data set, when read in the context of the other two data sets, suggests that an elevated arsenic level postpones the development of cancers that would otherwise occur. Once the extra arsenic is no longer added, these postponed cancers develop. This applicant claims that, these cancers are postponed further by the continued daily addition of arsenic at levels corresponding to 25 to less than 75 μg/L in drinking water: a lifetime of this arsenic exposure would postpone a substantial fraction of cancers until after the individual's death; thus, arsenic becomes classified as an anti-carcinogen, more particularly a cancer prevention agent.
2. Common sense allows for arsenic to be added to drinking water, under conditions described in the invention.
3. The reason the invention is superior to EPA claims on arsenic is the reliance of this invention on actual cancer and heart disease mortality data in the 0 to less than 75 μg/L exposure range. EPA's analysis is based on extrapolation of high dose arsenic data to low dose, with very broad cancer exposure groupings: this is called modeling. A fundamental rule of science says that when real data contradict a model, the model – EPA's model – must be rejected. EPA's regulatory question was whether the arsenic standard should be kept at 50 μg/L or be lowered. In the Agency analysis, the lowest exposure category was 0 to 100 μg/L, which prevented any analysis from distinguishing a cancer response pattern within this exposure range. The Taiwan data set allows for the separate analysis of lung, liver and bladder cancers within the 0 to 100 or 0 to 75 μg/L range, not as the examiner claims. It is very likely that certain cancers are more likely to be impacted by the invention than others. "The reduction of total cancers" as a measure logically is more valuable than the reduction of any individual cancer classification, because "total cancers" is more inclusive of other cancer effects and risks than individual cancer assays are. The common failure not to look beyond the impact of a chemical exposure on more than the single cancer classification is classically illustrated by the example of tamoxifen: approved by FDA for breast cancer prevention in women likely to get breast cancer even

though the tamoxifen treatment causes an increase in uterine cancers greater than the breast cancer decrease. There are always issues in extending the results from a single study to a national US population. EPA had no problem in extending (misread) bladder cancer data to the national US population. Having two distinct populations report significant total cancer benefits attached to arsenic levels near 50 μg/L gives a patent claimant far greater confidence in his claims. The Taiwan and Utah data sets represent two very different populations – by race, smoking and drinking habits, diets, and longevity – both reveal cancer benefits, not identical but similar and strong, associated with arsenic levels "around 50 μg/L."

4. The nature of the invention is clearly specified, according to the examiner.
5. This invention acknowledges the prior art, which shows arsenic is clearly associated at high dose with cancer, heart disease and other health issues. This invention does not rely on this prior art, which adds to its novelty. Obviously, this invention works with arsenic in aqueous solution, without regard to valence or particle size.
6. No comment needed.
7. The inventor refers to data that make his case both with respect to certain individual cancers and larger cancer groupings, including "total cancers." Significant changes in "total cancers" is a more relevant measure for cancer prevention (and causation) than in individual cancer categories for human health. The reviewer is probably accustomed to government use of an increase in an individual cancer classification rather than total cancers associated with exposures to a chemical: often cancer rate increases which would be valued as "significant" in one tissue, would "not be significant" if measured in all tissues: so "total cancers" is not a commonly used measure by Regulatory Agencies. If there is any skew or bias in data analysis, criticism might better be directed at Federal Agencies which focus on single tissues or single health endpoints and ignore the broader health issues associated with the total body. The examiner also insists that empirical screenings occur over a long period of time. The Taiwan data set follows villagers in 42 villages over the course of 13 years, from 1973-1986, exposed for years before then to water from the same well or wells; the Millard, Utah data set followed all the individuals in that county over a period of over 100 years; the Cuzick patients were followed for as long as more than 20 years following the start of treatment, though the interesting results were noted in the first ten years.
8. The claim is directed to the "reduction of total cancer deaths and, separately, heart disease deaths" NOT as the reviewer claims, "the **total reduction** in cancer and/or heart disease related deaths...." [Emphasis added.]